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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,407	12/13/2001	Kevin P. Baker	P2830P1C61	8089

30313 7590 05/14/2004

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EXAMINER	
NICKOL, GARY B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/017,407	BAKER ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/30/02,10/25/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 28-47 are pending.

DETAILED ACTION

Priority

A review of the parent applications reveals that the claimed nucleic acid (SEQ ID NO:305 that encodes the PRO1558 protein) having utility in gene amplification assays has earliest priority to February 18, 2000 as disclosed in PCT/US00/04342. If applicant disagrees with any rejection of claims 28-47 set forth in this office action based on examiner's establishment of a priority date of February 18, 2000 for the instant claims in application serial number 10/017407, applicant is invited to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.

Claim Objections

Claims 28-33, 38-39, and 41 are objected to for reciting: "the nucleic acid sequence in Figure 171 (SEQ ID NO:305)" and "the full-length coding sequence of the nucleic acid sequence shown in Figure 171 (SEQ ID NO:305)" as there does not appear to be a patentable distinction between the two sequences since both sequences comprises SEQ ID NO:305. Hence, this recitation appears to incorporate substantially duplicate claimed subject matter.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 46, as written, does not sufficiently distinguish over cells as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 42 is indefinite for reciting "stringent conditions" since said conditions are not defined in the claims. Furthermore, the specification (page 309) does not contain a limited definition of what is defined by such conditions. The speciation only teaches that which may be identified as stringent conditions. Thus, stringent conditions read on the full range of stringent conditions, that is from very permissive to very high stringency. Hence, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention and would not be able to determine the metes and bounds of the claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-33, 36-37, 41-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth the following: an isolated nucleic acid sequence comprising SEQ ID NO:305, and isolated nucleic acid sequence encoding the polypeptide of SEQ ID NO:306, or an isolated nucleic acid sequence comprising the full-length coding sequence of the cDNA deposited under ATCC accession number 203312, and therefore the written description is not commensurate in scope with the claims which read on nucleic acid variants and or fragments of SEQ ID NO. 305 and or nucleic acids encoding variants and or fragments of SEQ ID NO:306 including those that only encode extracellular domains.

The claims are drawn to isolated nucleic acid sequences having at least 80%, 85%, 90%, 95% or 99% sequence identity with a particular disclosed sequence. The claims do not require that the encoded polypeptide (and or nucleic acid sequence) possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of nucleic acids and or encoded polypeptides defined only by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus.

The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. Further, there is no identification of any particular portion of the structure that must be conserved. Also, the specification fails to provide a written description of the amino acid sequences within SEQ ID NO:306 that form the extracellular domain. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus or extracellular domains.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated nucleic acid sequence comprising SEQ ID NO:305, and isolated nucleic acid sequence encoding the polypeptide of SEQ ID NO:306, or an isolated nucleic acid sequence comprising the full-length coding sequence of the cDNA deposited under ATCC accession number 203312, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 28-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized in *Ex parte* Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claimed invention is broadly drawn to isolated nucleic acids, including those comprising SEQ ID NO:305 and further encoding the polypeptide of SEQ ID NO:306. The specification appears to contemplate some type of diagnostic utility for the claimed invention according to the gene amplification studies as set forth on page 494. However, one of ordinary skill in the art would not know how to predictably use the claimed invention based on the guidance and teachings in the specification. In particular, the specification teaches that several primary lung tumors exhibited amplification of the PRO1558 gene. For example, see page 503, column 12. The ΔCt for HF-000840 and HF000842 was 1.39 and 1.24, respectively. This would appear to indicate an approximately 2 fold-amplification of PRO1558 *relative to normal* . However, what exactly constitutes normal and/or a negative control? In the instant case, the specification teaches that the negative control consisted of DNA isolated from the *blood* cells of ten normal healthy individuals (page 494, line 31; page 500, line 22). However, the specification is silent as to any correlation between DNA isolated from lung cancer and DNA isolated from the blood. How exactly is DNA isolated from the blood considered a control especially since it is not clear what type of blood cells were isolated? Furthermore, the specification is silent on whether or not PRO1558 is shed or secreted into the blood stream under normal and or cancerous conditions. Thus, applicants are attempting to compare the expression of PRO1558 in lung tumor specimens versus its expression in a non-related tissue. However, to those of ordinary skill in the art of oncology, a true negative control would more than likely comprise the analysis of the expression of PRO1558 in the corresponding normal tissue, i.e. normal lung tissue, thus excluding the possibility of false-positive results. Many proteins, including PRO1558, are expressed in a variety of normal tissues and diseased tissues. Therefore,

one needs to know, e.g., that the claimed sequence is present only in cancer tissue to the exclusion of the corresponding normal tissue.

Thus, based on the lack of guidance and exemplification in the specification, and in view of the state of the art, one of ordinary skill in the art would not be able to use the invention in a predictable manner. Thus, it would require undue experimentation to practice the invention as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by EST Sequence Databases, Accession No. AA584408, September 26, 1997.

The reference teaches a human cDNA that is at least 10 nucleotides in length (Claim 43) and has 620 base pairs that has an overall match of 55.5% with SEQ ID NO:305. Inherently, the sequence of the prior art would hybridize under stringent conditions to the nucleic acid sequences claimed in Claim 41 because the nucleic acid sequences claimed in claim 41 all include SEQ ID NO:305.

No claim is allowed.

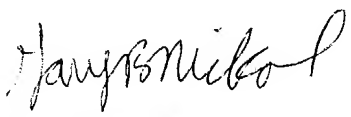
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

May 11, 2004



GARY NICKOL
PRIMARY EXAMINER